UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

No. 17-cv-01969-PJS-TNL

QXMédical, LLC,

Plaintiff and Counterclaim Defendant,

v.

Vascular Solutions, LLC; Teleflex Innovations S.à.r.l.; and Arrow International, Inc.,

Defendants and Counterclaim Plaintiffs.

MEMORANDUM IN SUPPORT OF QXMÉDICAL, LLC'S MOTION FOR SUMMARY JUDGMENT

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INTRODUCTION

Counterclaim Plaintiffs ("VSI") allege QXMédical, LLC's ("QXM's") Boosting Catheter infringes six patents: 8,048,032 ("'032 patent"); 8,142,413 ("'413 patent"); RE45,380 ("RE'380 patent"); RE45,760 ("RE'760 patent"); RE45,776 ("RE'776 patent"); and RE46,116 ("RE'116 patent"). As a matter of law, all patent claims asserted in this case are invalid or not infringed by QXM. QXM moves for summary judgment on the following grounds:

1. All asserted claims are invalid because the term "substantially rigid," which runs through each claim, is indefinite.

2. Three reissued patents (RE'760, RE'776 and RE'116) are invalid because they violate the recapture rule by improperly eliminating the "without a lumen" limitation from the original '032 patent.

3. QXM's Boosting Catheter does not infringe the '032, '413 and RE'380 patents because they require a pushrod "without a lumen," and the Boosting Catheter's shaft has a lumen.

4. QXM's Boosting Catheter does not infringe '032 claim 8, RE'380 claim 8, RE'760 claims 25 and 48, RE'776 claims 30 and 53, and RE'116 claim 25, all of which require the inner diameter of the distal tube to be "not more than one French smaller" than the inner diameter of the guide catheter with which the device is prescribed for use.

5. QXM's Boosting Catheter does not infringe RE'760 claim 25, RE'776 claims 25 and 52, RE'760 claim 48, and RE'116 claim 52, because portions of the Boosting Catheter's "tubular structure" are more rigid than the "side opening."

6. Claim 53 of RE'116 is invalid as anticipated by Patent No. 5,527,292 ("Adams").

The above issues present several independent bases for the Court to resolve this entire case. If the Court enters summary judgment for QXM on issue #1, the case is over. If the Court enters summary judgment for QXM on issues #2 and #3, the case is over. If

the Court enters summary judgment for QXM on issues #3, #4, #5, and #6, the case is over. For any or all of those reasons, the Court should grant summary judgment that QXM's Boosting Catheter does not infringe VSI's patents.

ARGUMENT

The Court shall enter summary judgment "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). The undisputed evidence below entitles QXM to summary judgment.

I. ALL ASSERTED CLAIMS ARE INVALID BECAUSE THE TERM "SUBSTANTIALLY RIGID" IS INDEFINITE

All asserted claims of the VSI patents are invalid because the term "substantially rigid" – a common element to each claim – is indefinite. VSI's claimed device has three basic segments: (1) a "substantially rigid" pushrod; (2) a "flexible" tube; and (3) a side opening to the tube. (*See, e.g.*, '032 claim 3 and RE'760 claim 25.) The Court accepted VSI's claim construction that "substantially rigid" means "rigid enough to allow the device to be advanced within the guide catheter." (Order [Dkt. #102], at 15.) But the distal tube, which is "flexible," is also "rigid enough to allow the device to be advanced within the guide catheter." There is, therefore, no meaningful distinction that would enable a person of skill in the art to distinguish "substantially rigid" from "flexible."

A. Indefiniteness Standard

"[A] patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 901 (2014). "[A] claim term is indefinite if it leave[s] the skilled artisan to consult the unpredictable vagaries of any one person's opinion." *Dow Chem. Co. v. Nova Chemicals Corp. (Canada)*, 803 F.3d 620, 635 (Fed. Cir. 2015) (internal quotation marks and citation omitted). "Even if a claim term's definition can be reduced to words, the claim is still indefinite if a person of ordinary skill in the art cannot translate the definition into meaningfully precise claim scope." *Halliburton Energy Servs. v. M-I LLC*, 514 F.3d 1244, 1251 (Fed Cir. 2008). Whether a patent is invalid for indefiniteness is a question of law. *Cardiac Pacemakers, Inc. v. St. Jude Medical, Inc.*, 296 F.3d 1106, 1113 (Fed. Cir. 2002).

B. The Court's Claim Construction

Although the Court has construed "substantially rigid," it remains indefinite.[1] After accepting VSI's argument that "substantially rigid" means "rigid enough to allow

[1] This is a problem of VSI's creation. VSI insisted "substantially rigid" should be construed according to its function, as opposed to its plain and ordinary meaning. (Hrg. Trans. [Dkt. #79] 108:17-112:7.) If given a plain meaning construction, QXM would not infringe. The exemplary "rigid" pushrod in the VSI patents is approximately three times as rigid as the allegedly "substantially rigid" proximal shaft in QXM's Boosting Catheter. (Declaration of Courtland Merrill ("Merrill Decl.") Ex. 21, ¶ 134.) If measured against the standard for rigidity in the VSI patents, the Boosting Catheter's proximal shaft is not "substantially rigid." (*Id.*, ¶¶ 118-136.)

the device to be advanced within the guide catheter," the Court noted that VSI's "victory may be short-lived – or even pyrrhic." (Order [Dkt. #102], at 15.) The Court summarized QXM's argument that the "flexible" tube fits VSI's definition of "substantially rigid." (*Id.*) The Court then wrote:

> QXMédical would have a compelling argument, but for one problem: The evidence in the record simply does not allow the Court to determine whether the factual premises of the argument are true. . . . At this point, then, the Court cannot conclude that Vascular Solutions's proposed construction of "substantially rigid" would capture anything that the patents describe as "flexible."

(*Id.* at 16-17.) The undisputed evidence now in the record conclusively establishes that the "flexible" tube is "rigid enough to allow the device to be advanced within the guide catheter."

C. "Substantially Rigid" Is Indefinite

The undisputed evidence shows that VSI's construction of "substantially rigid" captures portions of the Boosting Catheter that are indisputably "flexible." QXM's technical expert, Brian Brown, performed a catheter advancement test using a portion of the Boosting Catheter's distal tube that VSI agrees is "flexible." (Merrill Decl. Ex. 1, ¶ 456.) Brown took samples of that tube and linked them together to create a full-length "flexible" catheter long enough to extend 15 cm beyond the distal end of the guide catheter. (*Id.*, ¶¶ 457-59.) Brown placed a guide catheter in a simulated coronary artery, and pushed the proximal end of the full-length "flexible" catheter through and beyond the guide catheter into the simulated coronary artery. (*Id.*, ¶¶ 460-61.) Brown's test established that the "flexible" material comprising the Boosting Catheter tube is "rigid

enough to allow the device to be advanced within the guide catheter." (*Id.*, *see also* ¶¶ 462-64 (describing secondary "reversed advance-ability" test to confirm results).)[2]

VSI's technical expert, Peter Keith, does not dispute the results of Brown's tests. Keith does not deny that the flexible distal tube of the Boosting Catheter, if extended for the entire length of the device, is rigid enough to advance the device through a guide catheter. (Keith Dep. 160:19-161:23.)[3] Keith also does not deny that, under the construction of "substantially rigid," things that are "flexible" would also fall within the definition of "substantially rigid." (*Id.* 163:9-164:3, *see also* 181:13-15 ("[F]lexibility and rigidity are tied together, so if you are looking at it for rigidity, you are also looking at it for flexibility.").)

Brown's test results and Keith's deposition testimony highlight the problem with the term "substantially rigid," as construed. "Rigid" and "flexible" are antonyms.[4] They

[2] This is precisely the test discussed during the claim construction hearing. (Hrg. Trans. [Dkt. #79] 106:4-21.)

[3] The deposition transcript of Peter Keith ("Keith Dep.") is attached to the Merrill Declaration as Exhibit 2.

[4] The claims and specification use "flexible" and "substantially rigid" to describe mutually exclusive portions of the claimed invention. "Substantially rigid" describes the proximal portion comparatively more rigid than the distal "flexible tip portion" ('032, '413, and RE'380, claim 1) or the flexible "tubular structure" (RE'776, claim 25; *see also* claim 52; RE'760, claim 25; and RE'116, claim 25). The tubular structure is "flexible" so it can be advanced into the narrow coronary arteries. (*See, e.g.*, '413 patent, claim 1 ("advancing a distal portion of the flexible tip portion distally beyond the distal end of the standard guide catheter and into the second artery").) VSI argued during prosecution that the rigidity of the proximal "substantially rigid" portion was distinguishable from the distal "flexible tip" portion. (Merrill Decl. Ex. 15 at 13.)

cannot have the same meanings. *See, e.g., Outside the Box Innovations, LLC v. Travel Caddy, Inc.*, No. CIV. A. 1:05-CV2482O, 2006 WL 6142860, at *9-11 (N.D. Ga. Sept. 18, 2006), *aff'd*, 695 F.3d 1285 (Fed. Cir. 2012) (recognizing the need to differentiate between terms "flexible," "generally rigid" and "generally semi-rigid"). Applying the Court's construction, a person of ordinary skill in the art is unable to determine the difference between "substantially rigid" and "flexible," or the boundaries of either term. *See Seattle Box Co. v. Indust. Crating & Packing, Inc.*, 731 F.2d 818, 820-21, 826 (Fed. Cir. 1984) (words of degree can be indefinite if the patent's specification fails to provide a standard for measuring the degree claimed). If the pushrod and the tube are both "substantially rigid" and "flexible," then those terms are entirely superfluous. VSI's requested construction of "substantially rigid" makes it impossible to draw the line between infringement and non-infringement. Accordingly, the Court should invalidate all asserted claims of the VSI's patents for indefiniteness.

II. RE'760, RE'776, AND RE'116 ARE INVALID BECAUSE THEY VIOLATE THE RECAPTURE RULE

Three of VSI's reissued patents (RE'760, RE'776, RE'116) are invalid because they violate the rule against recapture of subject matter surrendered during prosecution of the original application from which they arose. During protracted prosecution of the original '032 patent, VSI narrowed its claims to avoid prior art – first by describing the pushrod as "non-tubular" and "non-circular," and then as a "rail structure without a lumen." This was not an inadvertent "error"; VSI intentionally added the "without a lumen" limitation to get the claims of the '032 patent issued. When VSI obtained three

of the reissued patents, however, it removed the "without a lumen" limitation and reverted back to the broader original description ("substantially rigid portion" alone) that the Patent Office had previously rejected. VSI cannot recapture through reissued patents territory it surrendered.

A. The Recapture Rule

A patent holder may seek reissue of an existing patent that is inoperative or invalid as a result of "error." 35 U.S.C. § 251. "However, under the rule against recapture, 'a patentee is precluded from regaining the subject matter that he surrendered in an effort to obtain allowance of the original claims.'" *Greenliant Systems, Inc. v. Xicor LLC*, 692 F.3d 1261, 1263 (Fed. Cir. 2012) (quoting *N. Am. Container, Inc. v. Plastipak Packaging, Inc.*, 415 F.3d 1335, 1349 (Fed. Cir. 2005)). "[S]uch a surrender is not the type of correctable 'error' contemplated by the reissue statute." *Hester Industries, Inc. v. Stein, Inc.*, 142 F.3d 1472, 1480 (Fed. Cir. 1998).

The recapture rule involves three steps. *Greenliant*, 692 F.3d at 1267. First, the Court must determine if the reissue claims are broader than the original claims. *Id.* Second, the Court must determine if the broader aspects of the reissue claims relate to subject matter surrendered in the original patent prosecution. *Id.* Third, the Court must determine if the element of the reissue claims at issue was materially narrowed in some respect. *Id.*

Whether a reissued patent is invalid according to the recapture rule is a question of law. *In re Mostafazadeh*, 643 F.3d 1353, 1358 (Fed. Cir. 2011). The Court may decide this issue on summary judgment. *See Greenliant*, 692 F.3d at 1263 (affirming summary

judgment that reissued patents were invalid under the recapture rule); *MBO Laboratories, Inc. v. Becton, Dickinson & Co.*, 602 F.3d 1306, 1308 (Fed. Cir. 2010) (same); *N. Am. Container*, 415 F.3d at 1338 (same).

B. VSI's Reissued Patents Are Broader than the Original '032 Patent

With respect to the first step of the recapture analysis, VSI's reissued patents are broader than the original '032 patent from which they stem. The '032 patent required the pushrod be "without a lumen." ('032 claim 1 (10:40-41); *see also* '413 claim 1 (10:54-55); RE'380 claim 1 (11:4).) Each asserted claim of the RE'760, RE'776, and RE'116 reissued patents eliminated that limitation, broadening the claims to now cover devices with pushrods that may or may not have a lumen. (RE'760 claims 25 and 48; RE'776 claims 25, 52, and 53; RE'116 claims 25 and 52.) "A reissue claim that deletes a limitation or element from the patent claims is broader in that limitation's aspect." *In re Clement*, 131 F.3d 1464, 1468 (Fed. Cir. 1997). *See also Mostafazadeh*, 643 F.3d at 1361 (reissued patent that eliminated original "circular shape" requirement was invalid); *N. Am. Container*, 415 F.3d at 1350 (reissued patent that eliminated requirement that "inner walls" be "generally convex" was invalid); *Pannu v. Storz Instruments, Inc.*, 258 F.3d 1366, 1371 (Fed. Cir. 2001) (reissued patent that eliminated "circular arc" requirement was invalid).

C. VSI Surrendered Coverage over Pushrods <u>with</u> "Lumens"

As to the second step of the recapture analysis, the Court looks to the prosecution history to determine if the patentee surrendered particular subject matter. *Clement*, 131 F.3d at 1469. Surrender occurs if an objective observer would conclude that the

patentee made an amendment or argument in order to overcome prior art and obtain the patent. *Greenliant*, 692 F.3d at 1267. Here, the prosecution history establishes a prima face surrender of devices having a lumen.

On May 3, 2006, VSI filed the application that eventually led to the '032 patent. (Merrill Decl. Ex. 3.) VSI's initial claims described the pushrod of the device as merely a "substantially rigid portion":

> a substantially rigid portion proximal to the reinforced portion, the substantially rigid portion including a partially cylindrical portion defining an opening along a side thereof, the opening extending substantially along at least a portion of a length of the rigid portion;

(*Id.* at 24-25 (claim 8).)

On December 5, 2008, the Patent Office rejected all of VSI's initial claims as obvious in light of the prior art: Niazi combined with Solar. (Merrill Decl. Ex. 4 at 3.) Niazi discloses a catheter-within-catheter arrangement. (Merrill Decl. Ex. 17 at Fig. 6 and 6:45-54.) Solar discloses a rapid exchange balloon catheter with a pushrod, described as "advancement member 5." (Merrill Decl. Ex. 18, Fig. 1 and ¶ 0025.) Solar's "advancement member 5" is colored green in the image below with color added for clarity.

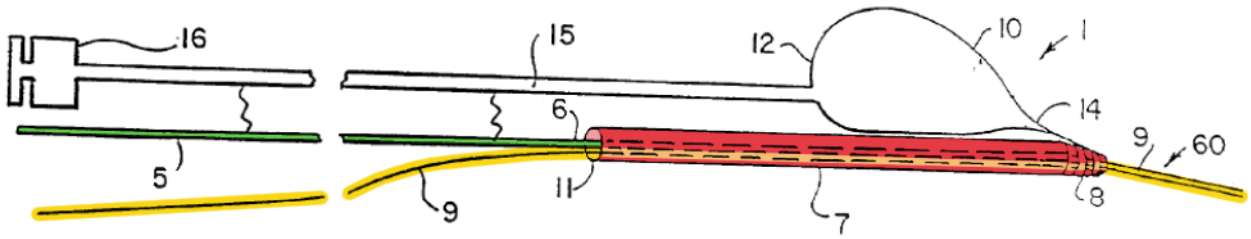


FIG. 1

(*Id.*, Fig. 1.) Solar's pushrod is "formed of a flexible wire, or alternatively, of spring hollow hypotube." (*Id.*, ¶ 0025.) There is no dispute a hypotube has a lumen. (Keith Dep. 22:21-22 (a hypotube is a "hollow metal shaft").) Over the next several months, the Patent Office rejected VSI's application two more times based on Solar and Niazi. (Merrill Decl. Ex. 5 at 6 (claim 8); Ex. 6 at 3; Ex. 7; Ex. 8 at 3-4.)

On February 19, 2010, VSI filed new claims. (Merrill Decl. Ex. 9 (claims 28, 56, 57) p. 3, 10, 12.) This time, VSI described the pushrod as "an elongated structure . . . having a non-circular cross-section." (*Id*. (emphasis added).) Again the examiner rejected the claims based on Niazi and Solar. (Merrill Decl. Ex. 10 at 5.) The examiner explained it would have been obvious to modify Solar's pushrod "to be non-circular . . . because a non-circular cross-section would have the ability to perform the same function as the rod taught by Solar with only the expected result of minimizing the profile of the rod inside the device." (*Id.* at 5.)

On June 28, 2010, VSI again filed new claims. (Merrill Decl. Ex. 11, Claims 58-77.) VSI's new claims described the pushrod as a "substantially rigid portion . . . defining a non-tubular structure having a maximal cross-sectional dimension at a proximal portion that is non-circular." (*Id.*, claims 58 and 67 (emphasis added).) VSI added the "non-tubular" and "non-circular" limitations to distinguish Solar, and disputed the examiner's conclusion Solar's pushrod would perform the same function as VSI's claimed "non-circular" pushrod. (*Id.* at 10-11.)

On July 30, 2010, the Patent Office rejected VSI's claims for obviousness and lack of written description. (Merrill Decl. Ex. 12 at 2, 3, 9.) Addressing VSI's prior art arguments, the examiner explained the pushrod in Solar could be made non-circular by flattening it into a rectangle. (*Id.* at 9.)

On October 8, 2010, VSI filed a response, arguing "the advancement member 5 of Solar is only discussed in terms of a 'flexible wire or, alternatively, a spring hollow hypotubing.'" (Merrill Decl. Ex. 13 at 12 (quoting Solar ¶ 0025).) VSI argued neither the "flexible wire" nor "hollow hypotubing" pushrods in Solar satisfied the claims' requirement of "non-circular" pushrod. (*Id.*) But the examiner again rejected the claims as obvious. (Merrill Decl. Ex. 14 at 4.) The examiner also rejected the "non-tubular" and "non-circular" limitations as "negative limitations" that lacked written description. (*Id.* at 2, 8 ¶ 4u.)

On February 22, 2011, VSI again amended the claims. (Merrill Decl. Ex. 15.) VSI removed the "negative limitations" describing the pushrod as "non-tubular" and "non-circular," and added a requirement that the pushrod be "more rigid . . . than the flexible tip portion":

> a substantially rigid portion proximal of and operably connected to, and more rigid along a longitudinal axis than, the flexible tip portion and defining a ~~non-tubular~~ structure having a maximal cross-sectional dimension at a proximal portion that is ~~non-circular and~~ smaller than the cross-sectional outer diameter of the flexible tip portion and having a length that, when combined with the length of the flexible distal tip portion, defines a total length of the device along the longitudinal axis that is longer than the length of the continuous lumen of the guide catheter,

(*Id.* claims 58, 67)

The Patent Office did not accept VSI's amendment until VSI further limited the shape of the pushrod. VSI's counsel agreed to an additional amendment requiring the pushrod have a "rail structure without a lumen." (Merrill Decl. Ex. 16 at 2.) As allowed, the amended claims read:

> a substantially rigid portion proximal of and operably connected to, and more rigid along a longitudinal axis than, the flexible tip portion and defining a ~~non-tubular~~ ~~structure~~ rail structure without a lumen and having a maximal cross-sectional dimension at a proximal portion that is ~~non-circular and~~ smaller than the cross-sectional outer diameter of the flexible tip portion and having a length that, when combined with the length of the flexible distal tip portion, defines a total length of the device along the longitudinal axis that is longer than the length of the continuous lumen of the guide catheter,

(*Id.*, amending independent claims 58 and 67.) The examiner explained in the notice of allowance that: "While many of the structures are known, the arrangement of a claimed rail structure . . . is not taught or suggested by the prior art." (Merrill Decl. Ex. 16 at 2.)

The prosecution history makes clear VSI included the "rail structure without a lumen" limitation (and the "non-tubular" and non-circular" limitations it replaced) to avoid Solar's hypotube or flexible wire pushrod. Patent Office guidelines presume an irrevocable surrender when an applicant adds a limitation following a prior art rejection, even if the applicant makes no argument regarding the need for the limitation. *See* Manual Patent Examining Procedure § 1412.02 [Dkt. #60-7] at 1400-27-28, Example #2. Thus, VSI is presumed to have surrendered coverage for pushrods with a lumen.

D. VSI Did Not Narrow its Reissued Claims

Step three of the recapture analysis cannot save VSI's reissued patents. A patentee can avoid recapture if it materially narrows the reissue claims at the same time it broadens them, such that it has not fully or substantially recaptured the surrendered subject matter. *Mostafazadeh*, 643 F.3d at 1358. But "the narrowing must relate to the subject matter surrendered." *Id.* at 1359.

VSI's RE'760, RE'776, RE'116 reissued patents do not narrow the claims in any way that relates to the shape of the claimed pushrod. *See, e.g.*, *Pannu*, 258 F.3d at 1372 ("The narrowing aspect of the claim on reissue, however, was not related to the shape of the haptics."). Three of the reissued patents no longer have the "without a lumen" limitation. They more broadly cover all "substantially rigid" pushrods – with or without a lumen. Those reissued patents are invalid under the recapture rule.

III. QXM'S BOOSTING CATHETER DOES NOT INFRINGE THE '032, '413 OR RE'380 PATENTS BECAUSE ITS SHAFT HAS A LUMEN

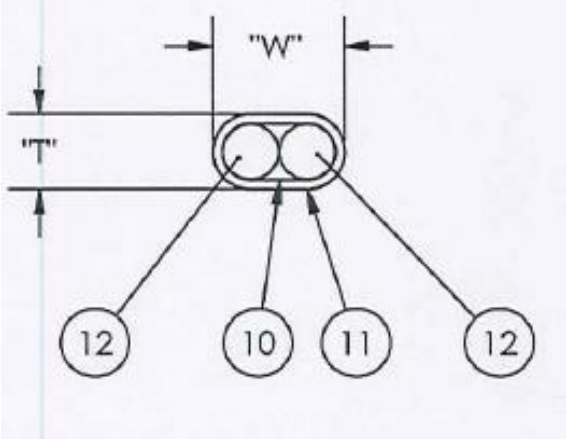
QXM's Boosting Catheter does not infringe any of VSI's patents (asserted claims 1 of the '032, '413 and RE'380 patents) that require a pushrod "without a lumen." The undisputed evidence establishes that the Boosting Catheter's shaft has a lumen, putting it outside the scope of these claims.

A. No Literal Infringement

The Court has construed "lumen" to mean "the cavity of a tube." (Order [Dkt. #102], at 25.) In adopting that construction, the Court referred to dictionary

definitions of "lumen" (*id.* at 24) and rejected VSI's narrower interpretation that a "lumen" must be large enough for a balloon or stent to pass through it. (*Id.* at 21-23.)

Applying the Court's construction, the shaft of the Boosting Catheter has a lumen and does not literally infringe the '032, '413 and RE'380 patents. The drawing below shows the cross-section of the Boosting Catheter's shaft:



(Merrill Decl. Ex. 19 at QXM006059.) As shown in the drawing, the Boosting Catheter shaft has two round wires (12) wrapped in sheath (11). (*Id.*) That leaves two voids between the wires and the sheath. (*Id.*) One void is filled with a bonding agent (10). (*Id.*) The other is empty and runs the length of the shaft. (Keith Dep. 182:6-8,183:11-184:10.)

The inside of the sheath is a "lumen" – i.e., a "cavity of a tube." (Merrill Decl. Ex. 21 ¶¶ 144-146.) The fact that the sheath lumen is partially filled with wires and a bonding agent does not change the fact that it is, by the Court's definition, a "lumen." The residual gap between the wires is also a lumen. (*Id.* ¶ 147.)

VSI's technical expert, Peter Keith, confirms the existence of a lumen in the Boosting Catheter shaft. Keith agrees the sheath of the Boosting Catheter surrounds the twin wires. (Keith Dep. 181:17-25.) Keith agrees the sheath is a "tube." (*Id.* 182:1-5.) Keith agrees there is at least some space between the sheath and the wires. (*Id.* 182:6-8, 183:11-184:10.) While Keith testified that the unoccupied "space" within the sheath is "tiny," he agrees the Boosting Catheter is different than the "solid" shaft described in the VSI patents, which has no internal space. (Keith Dep. 184:15-185:7, *see also* 185:11-186:9 (agreeing that Figures 1, 4, and 12 of the VSI patents show a proximal shaft without a lumen).) It is, therefore, indisputable that the Boosting Catheter has a lumen and avoids literal infringement of the '032, '413 and RE'380 patents under the Court's construction.

B. No Infringement under the Doctrine of Equivalents

VSI has argued that the Boosting Catheter infringes the "without a lumen" limitation under the doctrine of equivalents. But the doctrine of equivalents does not apply for multiple reasons.

First, the doctrine of equivalents cannot be used to eliminate or "vitiate" a claim element. *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 29-30 (1997). The doctrine of equivalents is especially inappropriate when the supposed "equivalent" is opposite of the claimed element. *See, e.g.*, *Asyst Technologies, Inc. v. Emtrak, Inc.*, 402 F.3d 1188, 1195 (Fed. Cir. 2005) ("unmounted" is not equivalent to "mounted"); *Hoganas AB v. Dresser Indus., Inc.*, 9 F.3d 948, 954–55 (Fed. Cir. 1993) ("solid fiber" is not equivalent to hollow "straw-shaped" element).

"With" a lumen is the opposite of "without," a feature critical to the invention's novelty. Rail structure "without a lumen" is the pushrod description the examiner found "not taught or suggested by the prior art." (Merrill Decl. Ex. 16 at 2.) The doctrine of equivalents is inapplicable when it would remove a limitation critical to the invention's novelty. *See, e.g., Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.*, 843 F.3d 1315, 1344 (Fed. Cir. 2016).

Second, prosecution history estoppel prevents a patentee from recapturing through the doctrine of equivalents subject matter that was surrendered during prosecution. *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 733-34 (2002). The doctrine presumptively applies where, as here, the applicant made a narrowing claim amendment related to patentability. *Id.* at 736-37. As discussed above, VSI amended its claims during prosecution to add the "without a lumen" limitation for patentability reasons. (*See supra* Section II.) Like the rule against recapture, prosecution history estoppel prohibits VSI from recapturing coverage over shafts with lumens. *See also Carnegie Mellon Univ. v. Hoffmann-LaRoche Inc.*, 541 F.3d 1115, 1129 (Fed. Cir. 2008) (where patentee specifically limited claim to one feature, it could not later claim another is equivalent); *Planet Bingo, LLC v. GameTech Int'l, Inc.*, 472 F.3d 1338, 1344 (Fed. Cir. 2006) (same). VSI cannot overcome the presumptive prosecution estoppel bar.

Third, patentees are barred from asserting an equivalency theory that would encompass, or "ensnare," the prior art. *Wilson Sporting Goods Co. v. David Geoffrey & Assoc.*, 904 F.2d 677, 683 (Fed. Cir. 1990). If VSI could pursue as equivalent shafts with lumens, the scope of the claims would cover Solar's "advancement member 5" made of

"spring hollow hypotube" that VSI avoided by amending the claims to require a pushrod "without a lumen." (Merrill Decl. Ex. 18 ¶ 0025.) VSI's evidence of equivalency is limited to the conclusory opinion of its expert that the Boosting Catheter "provid[es] a rapid exchange rail with a minimal cross-sectional profile." (Merrill Decl. Ex. 23, Appendix I at 11-12.) But Solar's prior art "hypotube" pushrod with a lumen also provides a rapid exchange rail with a smaller cross-section profile. (Merrill Decl. Ex. 18, Fig. 1.) Nothing passes through Solar's "lumen" in Figure 1.

Fourth, VSI cannot establish that the Boosting Catheter's lumen shaft performs in substantially the same way as the claimed pushrod "without a lumen." *See Graver Tank & Mfg. Co. v. Linde Air Products Co.*, 339 U.S. 605, 607 (1950). There is no infringement where the accused device performs the same function and achieves the same result but in a substantially different way. *Engel Industries, Inc. v. Lockformer Co.*, 96 F.3d 1398, 1406-07 (Fed. Cir. 1996).

Here, the Boosting Catheter's lumen shaft indisputably enables two wires to pass through it. (Merrill Decl. Ex. 21, ¶ 151.) No wires are capable of passing within the solid shaft of VSI's claimed device. QXM's twin-wire-inside-a-sheath design also makes the shaft more flexible in the axial, angular and longitudinal directions, minimizes stress concentration at the joint between the shaft and the tube, and enhances safety by making the device less prone to breakage and separation. (*Id.* ¶ 152.) The residual gap in the shaft enables the passage of fluid and is capable of inflating a balloon mounted on the shaft. (*Id.* ¶ 151.) VSI's claimed device "without a lumen" cannot inflate a balloon. (*Id.* ¶¶ 151-53.) Differences are substantial where, as here, an accused infringer

purposefully designed around a patent and made distinct changes for functional reasons. *Roton Barrier, Inc. v. Stanley Works*, 79 F.3d 1112, 1127 (Fed. Cir. 1996).

Differences are also substantial if the accused infringer obtained a patent on its unique elements. *Zygo Corp. v. Wyko Corp.*, 79 F.3d 1563, 1569-70 (Fed. Cir. 1996). Here, the Patent Office granted QXM a patent on its twin-wire shaft over VSI's patents disclosing a solid pushrod "without a lumen." (Merrill Decl. Ex. 20, References Cited.) Accordingly, the Boosting Catheter cannot infringe the '032, '413 or RE'380 patents, literally or under the doctrine of equivalents.

IV. THE BOOSTING CATHETER DOES NOT INFRINGE CLAIMS REQUIRING A LUMEN "NOT MORE THAN ONE FRENCH SMALLER" THAN THE COMPATIBLE GUIDE CATHETER

The '032 patent claim 8, RE'380 patent claim 8, RE'760 patent claims 25 and 48, RE'776 patent claims 30 and 53, and RE'116 patent claim 25, each require the "tubular structure" of the guide extension catheter to have a "cross-sectional inner diameter" that is "**not** more than one French smaller than the cross-sectional inner diameter of the lumen of the guide catheter." The Boosting Catheter does not infringe—directly or indirectly—because the inner diameter of the device is **more** than one French size smaller than the compatible guide catheter.

A. QXM's Instructions for Use Require its Boosting Catheter to be Used with a Guide Catheter that Does Not Meet the "One French" Limitation

VSI's infringement contentions regarding the "one French" requirement are limited to QXM's 6 French Boosting Catheter model BC57-150. (Merrill Decl. Ex. 22 at

9, 13-14, 22, 40, 45, 67.) VSI does not dispute QXM's three other models avoid infringement of this limitation. (*Id.*)[5]

There is no dispute QXM's 6 French Boosting Catheter has an inner diameter of 0.057 inches. (Merrill Decl. Ex. 23, Appendix D at 2-3; Ex. 19; Ex. 24.) One French equals 0.0131 inches. (Merrill Decl. Ex. 23, Appendix I at 26; Keith Dep. 85:18-86:3.) For the 6 French Boosting Catheter to infringe the "one French" limitation, it would need to be sold for use with a guide catheter that has an inner diameter of 0.070 inches or less.

QXM does not sell guide catheters. (Merrill Decl. Ex. 25, No. 1.) Rather, QXM sells the Boosting Catheter with Instructions for Use prescribing the sizes of compatible guide catheters that can be used with the device. (Merrill Decl. Ex. 24.) As an FDA regulated medical device, the Boosting Catheter's use is defined by its accompanying instructions. 21 C.F.R. §§ 801.4 (meaning of intended uses) and 801.5 (medical devices; adequate directions for use).

QXM's Instructions for Use explicitly caution physicians against using the Boosting Catheter with an incorrectly sized guide catheter. (Merrill Decl. Ex. 24 at 5 ("Precautions") and § 10.4 at 7 ("Device Usage").) The Instructions dictate that the 6 French Boosting Catheter must be used with a guide catheter having a minimum inner diameter of 0.071 inches:

[5] VSI abandoned a theory of infringement under the doctrine of equivalents for the "one French smaller" limitation. (Merrill Decl. Ex. 31.)

Table A: Boosting Catheter Specifications					
Catalog Number	**Part Number**	**Compatible Guiding Catheter**	**Compatible Sheath**	**Catheter *I.D.***	**Catheter *O.D.***
BC52-150	9005-201	≥ 6F [ID ≥ 0.066" / 1.68mm]	≥ 5F [ID ≥ 0.066" / 1.68mm]	0.052" / 1.32mm	0.064" / 1.63mm
BC57-150	9005-202	≥ 6F [ID ≥ 0.071" / 1.80mm]	≥ 5.5F [ID ≥ 0.072" / 1.83mm]	0.057" / 1.45mm	0.068" / 1.73mm
BC63-150	9005-203	≥ 7F [ID ≥ 0.078" / 1.98mm]	≥ 6F [ID ≥ 0.079" / 2.01mm]	0.063" / 1.60mm	0.076" / 1.91mm
BC72-150	9005-204	≥ 8F [ID ≥ 0.088" / 2.24mm]	≥ 7F [ID ≥ 0.092" / 2.34mm]	0.072" / 1.83mm	0.086" / 2.18mm

(Merrill Decl. Ex. 24 at QXM000088 (6 French identified in red).) Numerous 6 French guide catheters on the market have an inner diameter of 0.071 inches – which would make them compatible with a 6 French Boosting Catheter. (Merrill Decl. Ex. 26 at 17; Ex. 27 at 38 ("most common"); Ex. 23, Appendix S (44% of 6 French guide catheters sold with 0.071" I.D.))

The difference between the 0.057 inch inner diameter of a 6 French Boosting Catheter and the 0.071 inch inner diameter of a compatible guide catheter is 0.014 inches – which is greater than 0.0131 inches or one French. (Merrill Decl. Ex. 25, No. 4.)[6] Following QXM's FDA-compliant instructions, the accused Boosting Catheter has a

[6] The difference in IDs of non-infringing model BC52-150 and its compatible guide catheter is 0.014"—the same as accused model BC57-150. Therefore, VSI tacitly concedes that a difference in IDs of 0.014" or greater is outside the scope of the claim limitation.

"cross-sectional inner diameter" **more** than "one French smaller than the cross-sectional inner diameter of the lumen of the [compatible] guide catheter." (Keith Dep. 91:17-23.)

B. The Possibility of a Customer Ignoring QXM's Instructions for Use Does Not Make QXM Liable for Infringement

VSI argues that, despite QXM's instructions and warnings to customers, the 6 French Boosting Catheter directly infringes VSI's apparatus claims ('032 claim 8 and RE'776 claim 53) and indirectly infringes VSI's system and method claims (RE'380 claim 8, RE'760 claims 25 and 48, and RE'116 claim 25).[7] According to VSI, the 6 French Boosting Catheter is *capable* of being used with a guide catheter that satisfies the "one French" limitation, and QXM knows a customer may use the 6 French Boosting Catheter in that manner. Even if that were true, it is insufficient to establish infringement.

With respect to the apparatus claims, a party does not infringe such claims merely because it is *possible* to use the accused device in an infringing way. *ACCO Brands, Inc. v. ABA Locks Mfr. Co.*, 501 F.3d 1307, 1313 (Fed. Cir. 2007) (rejecting a "reasonably capable" standard for direct infringement). If the ordinary and intended use of the apparatus does not infringe, there is no infringement. *Accent Packaging Inc. v. Leggett & Platt, Inc.*, 707 F.3d 1318 (Fed. Cir. 2013); *High Tech Med. Instrumentation, Inc. v. New Image Indus., Inc.*, 49 F.3d 1551, 1555–56 (Fed. Cir. 1995).

[7] VSI does not claim direct infringement of the system and method claims because QXM does not make, use or sell a guide catheter or perform a method of using the Boosting Catheter with a guide catheter.

Here, the words of VSI's apparatus claims do not cover every device *capable* of being used with a guide catheter having inner diameter not more than one French smaller than the inner diameter of the device. Claim 8 of the '032 patent and claim 53 of the RE'776 patent require a device that must in fact be "*for use* with [such] a guide catheter." *See Typhoon Touch Tech., Inc. v. Dell, Inc.*, 659 F.3d 1376, 1380 (Fed. Cir. 2011) ("memory *for storing*" is not satisfied by memory merely "*capable of being configured* for storing"). The Boosting Catheter's Instructions for Use make clear that the 6 French Boosting Catheter is not "for use" with a guide catheter that would cause it to infringe the "one French" limitation.

With respect to VSI's system and method claims, VSI must show QXM specifically intended for customers to infringe those claims and took affirmative acts to encourage infringement.[8] *DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1305-06 (Fed. Cir. 2006). Evidence of QXM's mere knowledge that a customer may disregard the Instructions for Use and use the Boosting Catheter with a guide catheter having an inner diameter of 0.070 inches is not enough to establish inducement. *Takeda Pharm. U.S.A., Inc. v. W. Ward Pharm. Corp.*, 785 F.3d 625, 630 (Fed. Cir. 2015); *DSU Med.*, 471 F.3d at 1305-06.

[8] QXM cannot be liable for contributory infringement because it is indisputable that use of the accused 6 French Boosting Catheter according to its Instructions for Use with a 0.071" ID guide catheter is a substantial non-infringing use. *DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1303 (Fed. Cir. 2006) (contributory infringement requires evidence of the absence of substantial non-infringing uses).

The Boosting Catheter's Instructions for Use show that QXM explicitly discourages infringement of the "one French" limitation. (Merrill Decl. Ex. 24.) There is no evidence of an affirmative act by QXM to encourage users to disregard the Instructions for Use. *Takeda Pharm.*, 785 F.3d at 631 (no inducement where instructions actually described infringing mode but did not recommend or encourage its use).

V. QXM'S BOOSTING CATHETER DOES NOT INFRINGE CLAIMS REQUIRING THE "SIDE OPENING" TO BE MORE RIGID THAN THE "TUBULAR STRUCTURE"

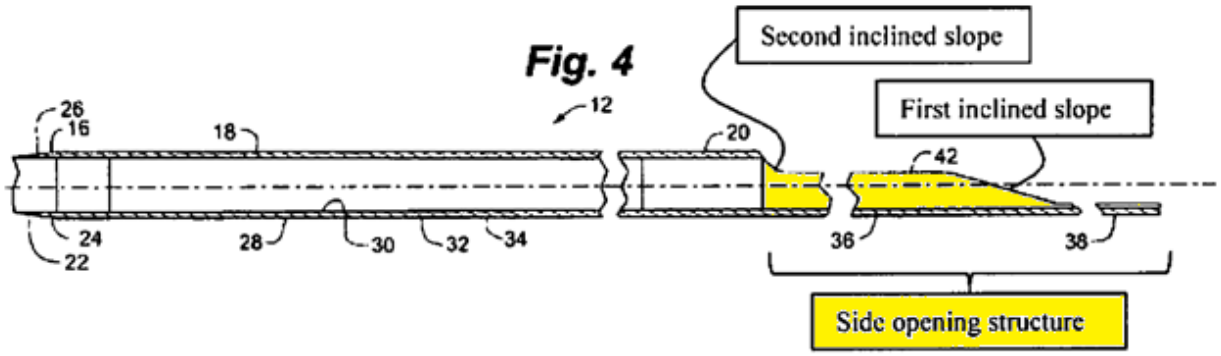
RE'760 claim 25, RE'776 claims 25 and 52, RE'760 claim 48, and RE'116 claim 52, each require the "segment defining the side opening" (or "a material forming" that segment) to be "more rigid than the tubular structure" (or a "distal end portion" of that structure). The Boosting Catheter does not satisfy these claim limitations because portions of the "tubular structure," including the "distal end portion of the tubular structure," are indisputably *more rigid* that the material forming the side opening of the device.

A. The "Side Opening" Does Not Include Any Full-Circumferential (Tubular) Structure

The Court has construed "side opening" to have its plain and ordinary meaning. (Order [Dkt. #102], at 26, *see also* 31-32 (construing "a material" forming the side

opening).) However, VSI cannot seem to decide where the "side opening" of the device is.[9]

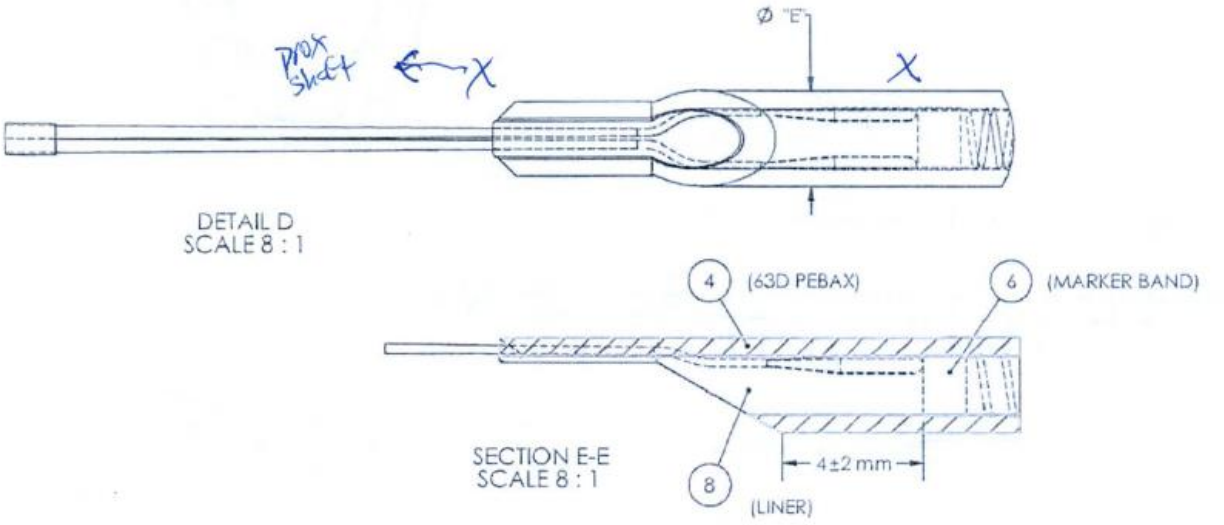
During prosecution, VSI submitted the following diagram to identify the "side opening structure" as the section of the device without any of the full-circumferential (tubular) structure:



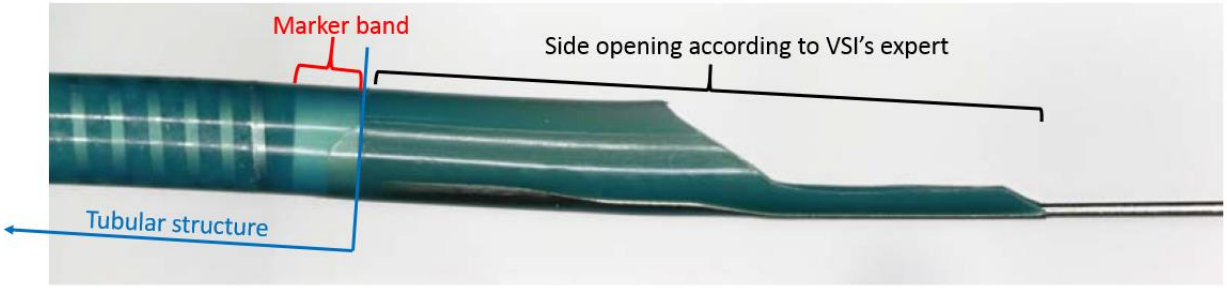
(Merrill Decl. Ex. 28 at 36 (color added).) VSI's expert refers to this area as the "geometric side" opening. (Keith Dep. 68:11-71:11.)

By contrast, in this lawsuit, VSI has identified the "side opening" of the Boosting Catheter as including a portion of the full-circumferential tubular structure between the actual opening and the marker band. (Keith Dep. 68:11-70:17.) VSI's expert, Keith, identified the "side opening" as the area between the two Xs in the drawing of the Boosting Catheter below:

[9] VSI's shifting definition of "side opening" suggests that it is indefinite. As VSI's expert Keith acknowledged, "different people [could] come to different determinations about what a side opening is and where it ends." (Keith Dep. 155:3-8.)



(*Id.* at 145:11-148:4, 149:5-152:3; Merrill Decl. Ex. 19 at QXM006060.) Keith testified that the "tubular structure" of the Boosting Catheter is everything from (and including) the proximal marker band to the distal end of the device. (Keith Dep. 151:16-152:3.) His location of the "tubular structure" and the "side opening" in the Boosting Catheter is shown in the annotated photograph below.



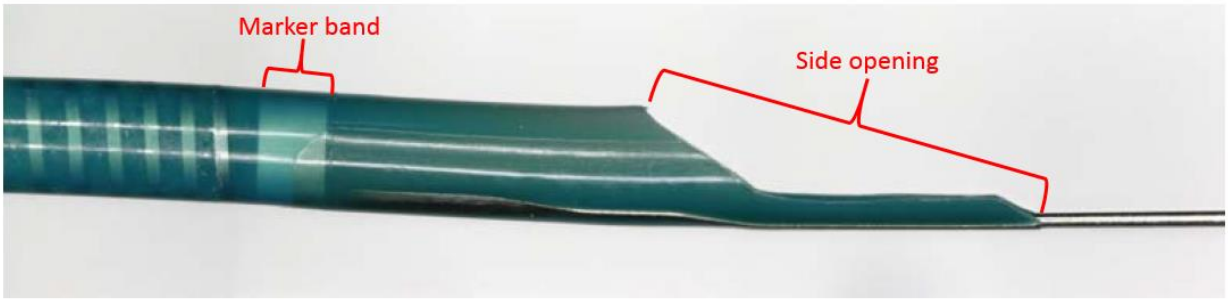
The definition of the "side opening" that VSI submitted to the Patent Office (i.e., the opening area that does not have any full-circumferential or tubular structure) is the correct one. The Court should reject VSI's litigation-driven, arbitrary definition of "side opening" that includes a portion of the full-circumferential tube. Regardless of

which definition applies, the Boosting Catheter does not infringe the patent claims describing the relative rigidity of the "side opening" and "tubular structure."

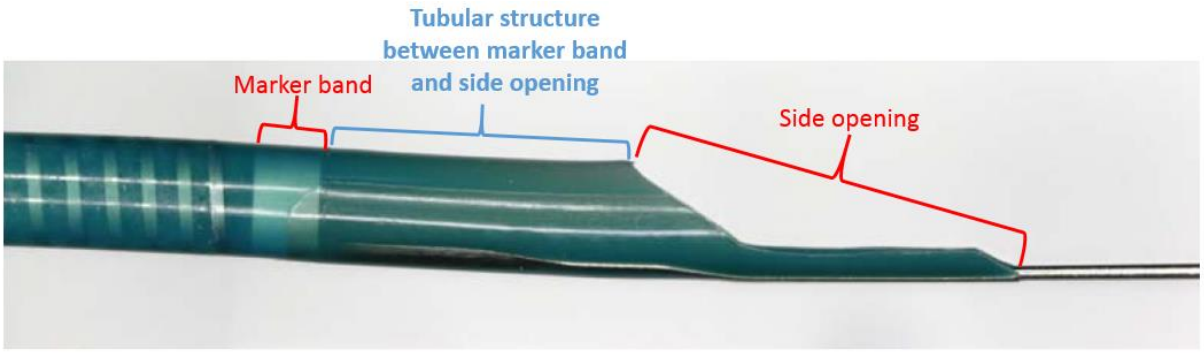
B. Portions of the Boosting Catheter's "Tubular Structure" Are <u>More</u> Rigid than the "Side Opening"

The section of the Boosting Catheter that VSI agrees constitutes the "tubular structure" contains two platinum marker bands, identified in the photographs below:

Distal tube of the Boosting Catheter

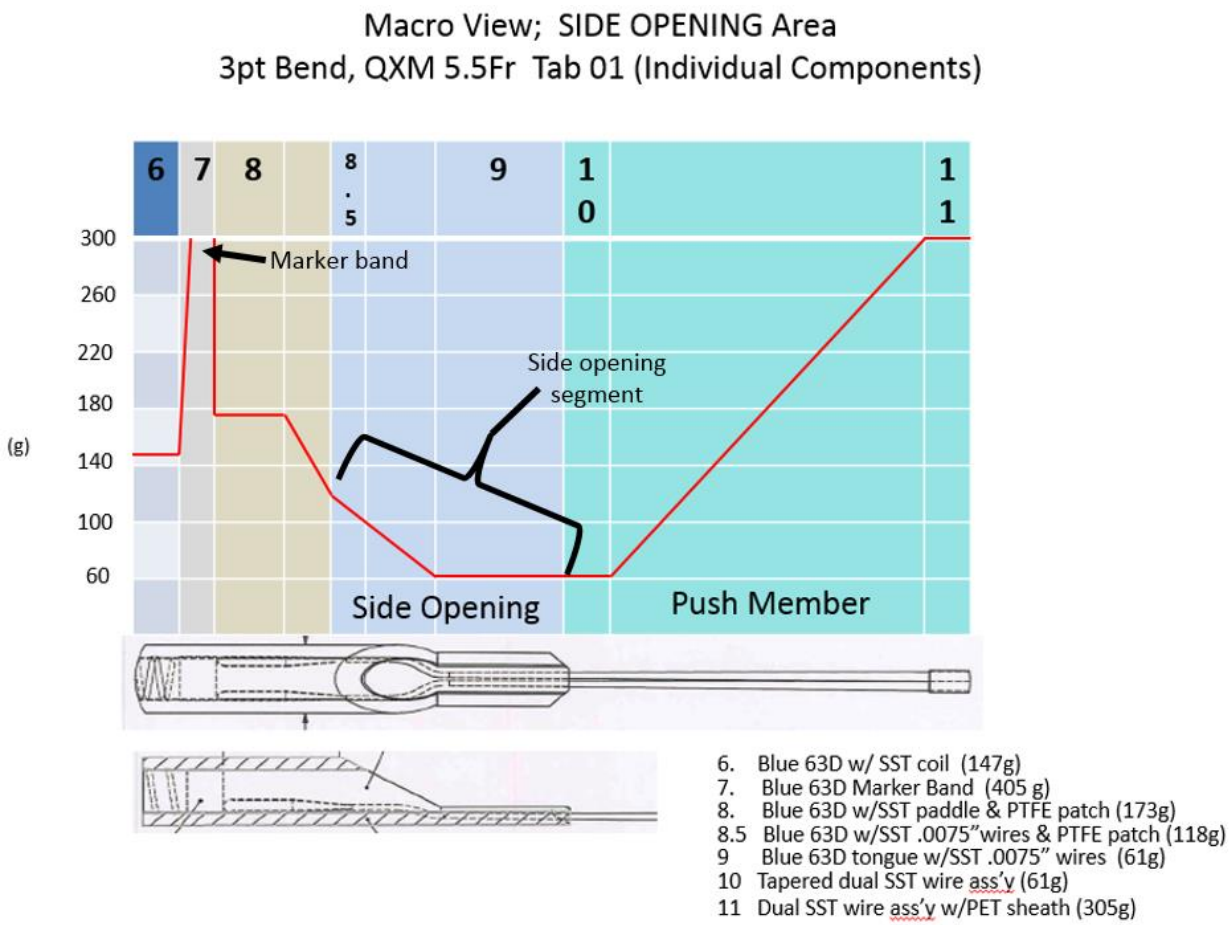


Side opening section of the Boosting Catheter



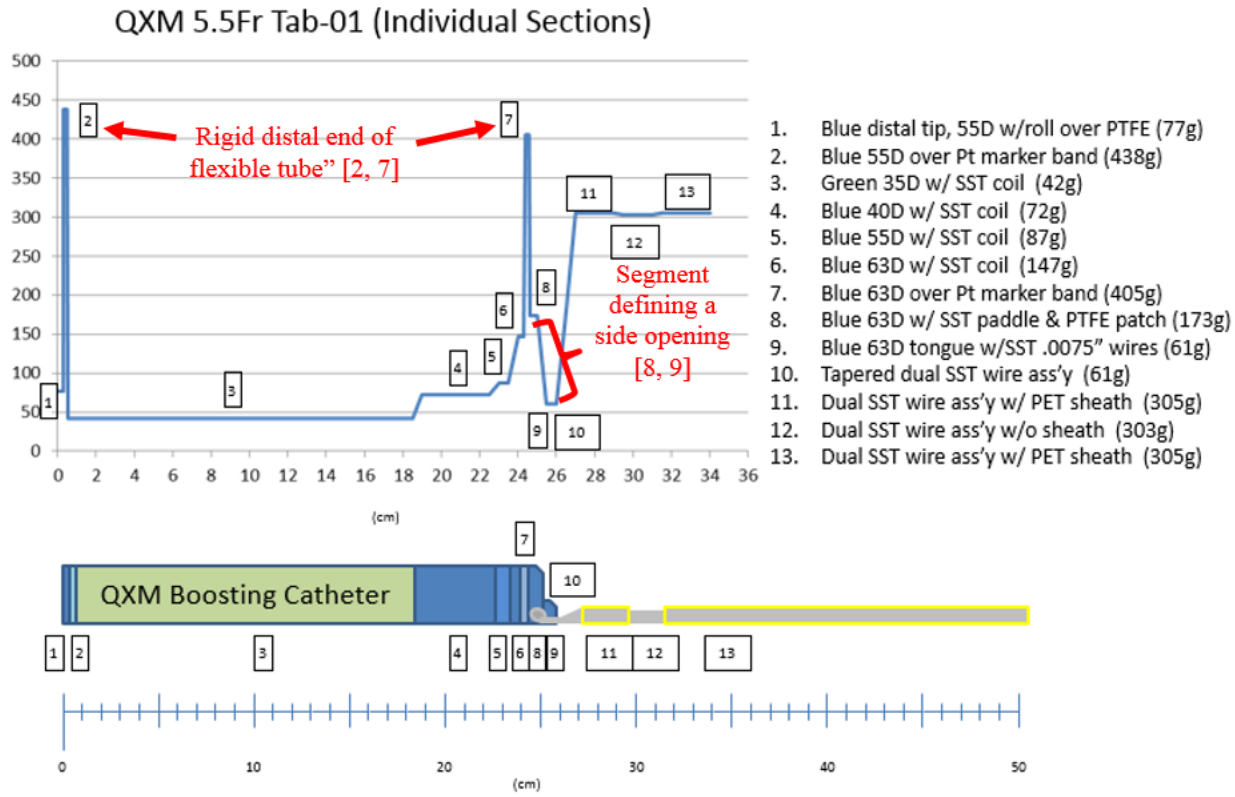
Side opening section of the Boosting Catheter

Assuming the "side opening" is only the "geometric side" opening without any tubular structure, the undisputed evidence establishes that the marker band portions of the Boosting Catheter's "tubular structure" are more rigid than its "side opening" segment. Three-point bend tests performed by QXM's expert, Brian Brown, confirm that conclusion. (Merrill Decl. Ex. 21, Ex. E at 20.) The chart below shows the results of Brown's three-point bend tests, focused on the side opening area compared to the most proximal marker band:



(Merrill Decl. Ex. 21, Ex. D at 4.)

Using VSI's expert's interpretation of "side opening," Brown's test results show that the marker band portions of the tubular structure are still more rigid than the "side opening segment":

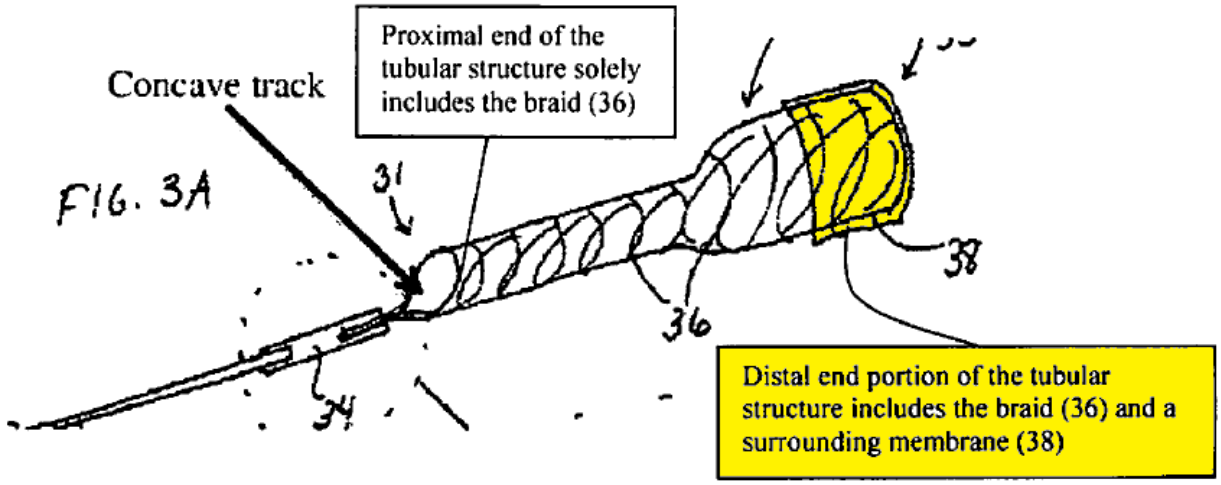


3-Point Bend – Boosting Catheter Results

(Merrill Decl. Ex. 21, Ex. D at 3.)

VSI's expert, Keith, agrees that Brown's three-point bend test is an appropriate way to measure rigidity. (Keith Dep. 166:13-21.) Keith does not dispute the accuracy of Brown's test results. (*Id.* at 170:23-171:2.) Keith agrees that the marker band portions of the Boosting Catheter are more rigid than the portion of the device that he interprets as the "side opening." (*Id.* at 171:10-172:24, 173:1-176:7.)

The fact that only the marker band portions are more rigid than the side opening is irrelevant. VSI argued during prosecution that a prior art reference that had a single rigid area along less than the entire length of the tubular structure was distinguishable from the claimed invention. (Merrill Decl. Ex. 28 at 37-39.) VSI included the annotated figure below from a prior art reference (Adams '280) to illustrate its argument.



(Merrill Decl. Ex. 28 at 38 (color added).) VSI argued the "surrounding member 38" in the prior art—a specific area, less than the entire length—was more rigid than the "segment defining a side opening," and, therefore, failed to satisfy the claim. (*Id.* at 37.) The marker bands in QXM's Boosting Catheter are also discrete sections, less than the entire length of the tubular structure, but more rigid than the "segment defining a side opening." Therefore, the tubular structure of QXM's Boosting Catheter falls outside the scope of the claims for the same reason VSI distinguished the prior art during prosecution.

VI. CLAIM 53 OF THE RE'116 PATENT IS ANTICIPATED BY ADAMS

As a matter of law, claim 53 of the RE'116 patent is invalid as anticipated by the prior art Adams patent. (Merrill Decl. Ex. 29.) "A patent is invalid for anticipation under 35 U.S.C. § 102 if a single prior art reference discloses each and every limitation of the claimed invention." *Purdue Pharma L.P. v. Epic Pharma, LLC*, 811 F.3d 1345, 1351 (Fed. Cir. 2016). The Adams patent issued in 1996 and constitutes prior art against all of the VSI patents. (Keith Dep. 216:16-19.) Adams describes a guide extension catheter in

rapid exchange, which is exactly what VSI describes as its invention. (Keith Dep. 47:23-48:6; Root Dep. 37:5-9.)[10] Adams discloses each element of claim 53 the RE'116 patent, rendering that claim invalid.[11]

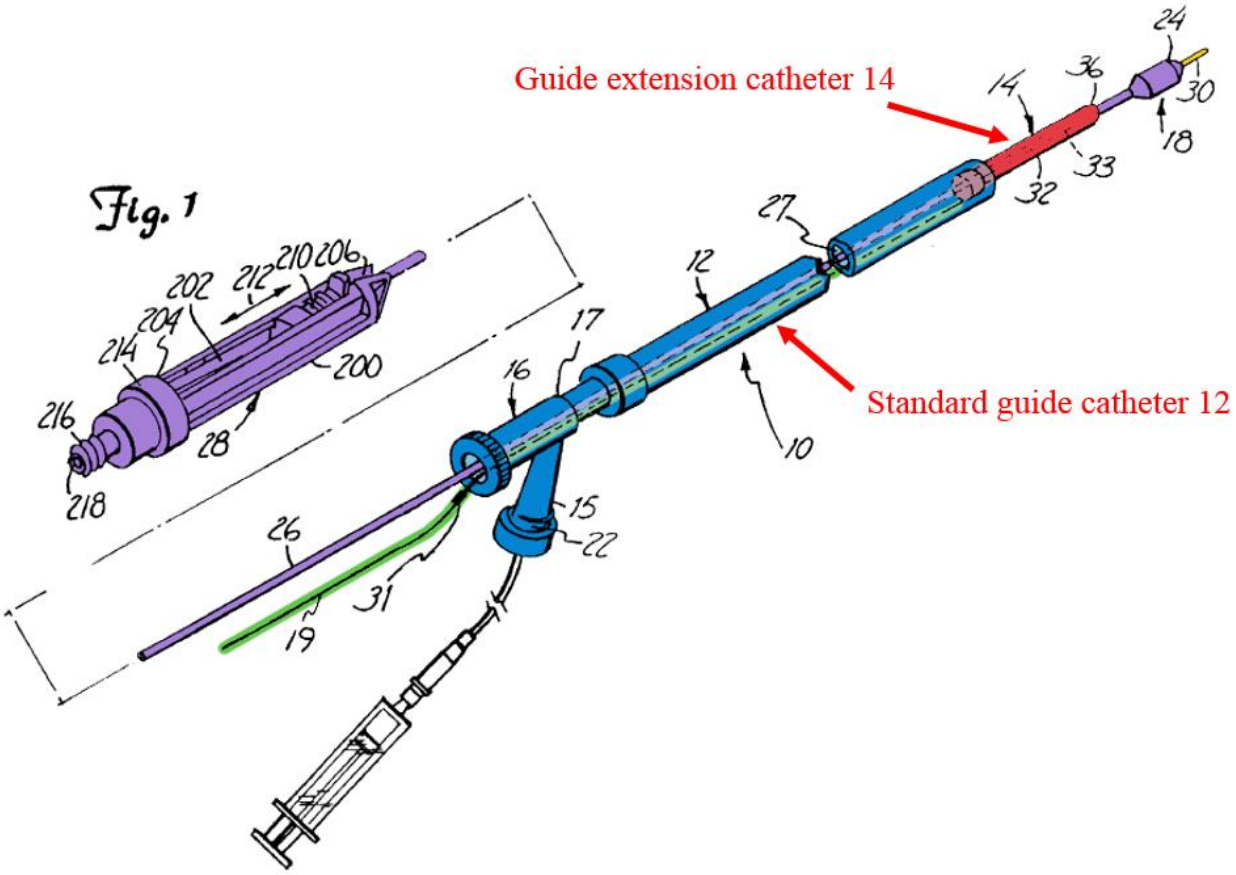
Claim 53 of the RE'116 patent depends on claim 52. The language of both claims is quoted in bold below.

A. Claim 52[i]: "A method, comprising: advancing a distal end of a guide catheter having a lumen through a main blood vessel to an ostium of a coronary artery; advancing a distal end of a guide extension catheter through the guide catheter, including advancing a distal end portion of a tubular structure of the guide extension catheter beyond the distal end of the guide catheter while a segment defining a side opening of the guide extension catheter remains within the guide catheter,"

Adams Fig. 1 shows a "guide catheter extension" (red 14) within the lumen of the guide catheter (blue 12):

[10] Excerpts from the deposition transcript of Howard Root ("Root Dep.") are attached to the Merrill Declaration as Exhibit 32.

[11] Summary judgment on claim 53 will "declutter" VSI's infringement allegations. Adams also anticipates as a matter of law every element of the 19 other asserted claims except for the following three limitations: (1) the angled or partially cylindrical side opening; (2) the "not one French smaller" limitation; and (3) the tubular structure having a "flexible cylindrical distal tip portion" "more flexible than … [a proximal] reinforced portion." None of these limitations is present in claim 53.



(Merrill Decl. Ex. 29, Fig. 1 (color added) and 6:1-11 (pushrod 19 and flexible tube 32 form "guide catheter extension 14"), *see also* 16:40-44, 22:35-40, and Fig. 12.) Adams explains Fig. 1 shows "guide catheter extension 14 . . . designed to extend beyond a distal end of [a] guide catheter 12 into the coronary arteries." (*Id.*, 6:1-11.)

Adams makes clear that, when the distal end of the guide extension is advanced beyond the distal end of the guide catheter, the proximal side opening of the guide extension remains within the guide catheter. (Merrill Decl. Ex. 29, 9:26-52, 15:58-64.) Adams Figs. 2 and 12 show the side opening in the guide catheter:

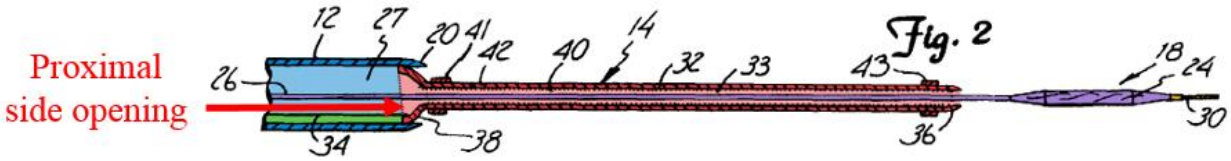


Fig. 2

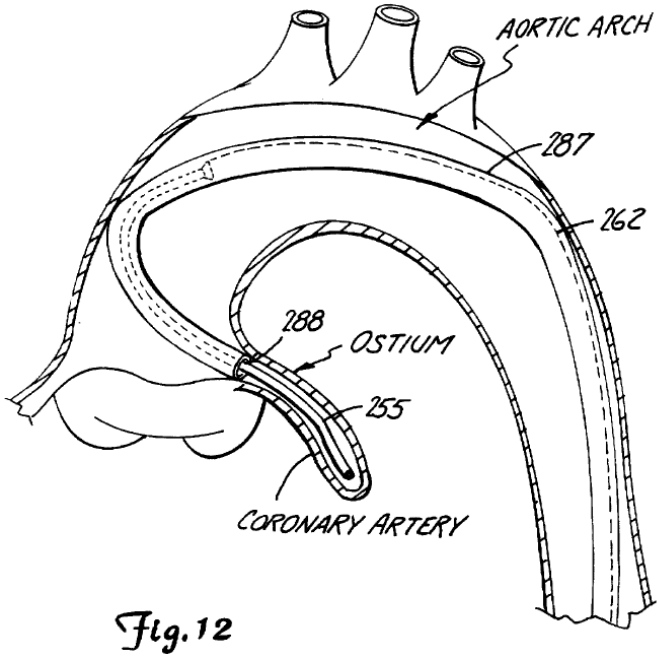


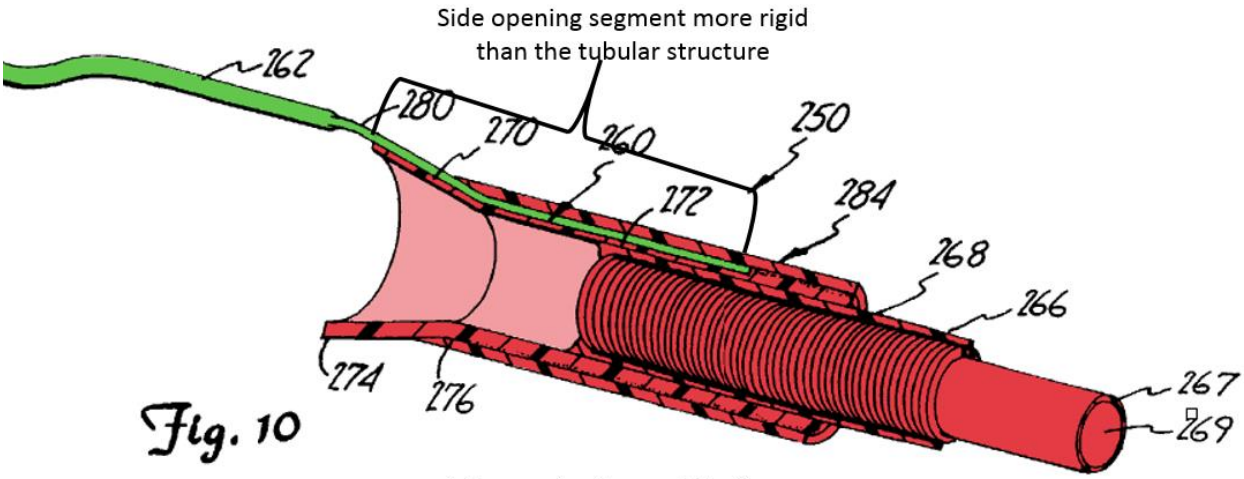
Fig. 12

(*Id.*, Figs. 2 (color added) and 12, *see also* Fig. 10; Keith Dep. 217:8-218:13 (admitting Adams Fig. 1 shows a "guide catheter extension" that "provides guide backup support in a way that allows you to advance various interventional cardiology devices deeper into the vasculature"); *id.* at 220:20-221:2 (admitting Adams Figs. 1 and 12 show a distal end portion of the "guide catheter extension" advanced beyond the end of the guide catheter while a side opening remains within the guide catheter); *id.* at 228:7-12 ("[W]hen you use the Adams patent to facilitate a guide catheter exchange, the guide catheter extension stays extended out of the distal end of the guide catheter."); *id.* at 228:13-19 ("[W]hile the guide catheter extension is extended from the guide catheter, a second treatment

device is then introduced to the guide catheter and then advanced into and from the distal end of the guide catheter extension.").)

B. Claim 52[ii]: "wherein the segment defining the side opening comprises a portion of the guide extension catheter that is more rigid than the distal end portion of the tubular structure;"

Adams discloses a pushrod formed of a nitinol wire. (Merrill Decl. Ex. 29, 16:8-24.) Figure 10 shows the distal end of the push rod embedded in the proximal end of the flexible tube. Using the definition of "side opening" that VSI uses for the Boosting Catheter, the push rod (green 262), side opening, and proximal end of the tube (red 255) of the Adams device are shown below:



Adams (color added)

(Merrill Decl. Ex. 29, Fig. 10 (color added), 14:1-6; *compare with* Ex. 19 at QXM006060 (QXM assembly drawing); Ex. 30, Ans. No. 16 (identifying the "side opening" of the Boosting Catheter).) The "side opening" portion of Adams is necessarily more rigid than the remaining distal portion of the flexible tube because the "side opening" contains the embedded pushrod 262 formed from nitinol wire.

C. Claim 52[iii]: "maintaining the distal end portion of the tubular structure of the guide extension catheter in position beyond the distal end of the guide catheter; and while maintaining the distal end of the guide extension catheter positioned beyond the distal end of the guide catheter, advancing a balloon catheter or stent at least partially through the guide catheter and the guide extension catheter and into the coronary artery, including advancing the balloon catheter or stent through a hemostatic valve associated with a proximal end of the guide catheter, along a substantially rigid segment of the guide extension catheter, through the side opening, and through the tubular structure."

Adams discloses that the guide catheter extension can be used to perform "guide exchanges," a technique involving advancing a balloon catheter through the guide extension. (Merrill Decl. Ex. 29, 9:26-52.) After an initial balloon is positioned across the stenosis, it often becomes "necessary to substitute a larger balloon than the balloon originally inserted." (*Id.* at 9:26-36.) The original balloon is withdrawn. (*Id.*) The guide catheter extension remains extended beyond the distal end of the guide catheter to establish a path "to or across the obstruction or stenosis and directing a substitute angioplasty balloon catheter thereto. . . . [T]he guide catheter 12 and the guide catheter extension 14 cooperate to direct the new angioplasty balloon catheter to the stenosis." (*Id.* at 9:36-41.)

Adams Figs. 1 and 2 show the balloon catheter traveling along the pushrod and through and beyond the side opening and tubular structure of the claimed guide extension catheter. (*Id.*, Figs. 1-2. *See also* Keith Dep. 221:18-222:5, 227:13-228:19 (describing the "catheter exchange" and admitting that Adams Fig. 1 shows a balloon catheter passing through the guide extension).) Adams discloses that the device can also be used with "guide wires and other coronary treatment devices," including stents. (Merrill Decl.

Ex. 29, 4:43; Keith Dep. 225:2-8 (conceding that Adams does not exclude the possibility of using the device with stents).)[12]

Adams also discloses the remaining elements in claim 52. Adams teaches use with a "hemostasis valve" that "provides hemostatic control for the guide catheter system." (Merrill Decl. Ex. 29, 5:16-29, *see also* 11:20-30.) As for the "substantially rigid portion," Adams' pushrod is preferably formed of nitinol – the same material VSI discloses for its pushrod. (*Id.*, 16:8-24; '032 patent 6:36.) Moreover, the Adams pushrod is sufficiently rigid to advance the device within the guide catheter, thereby meeting the Court's claim construction of "substantially rigid." (Merrill Decl. Ex. 29, 15:7-24.)

D. Claim 53: "The method of claim 52, wherein advancing the distal end of the guide extension catheter through the guide catheter includes positioning the segment defining the side opening within the guide catheter for receiving the treatment catheter."

As explained above, Adams discloses that the side opening of the claimed device is positioned within the guide catheter for receiving the treatment catheter (e.g., a balloon) when the distal end of the guide extension is advanced through the guide catheter. Accordingly, Adams indisputably anticipates every feature of RE'116 patent claim 53 and the independent claim 52 on which it depends. Claim 53 is invalid as a matter of law.

[12] VSI's own Guideliner V3 has the same inner diameter (0.046 inches) as the Adams device, and it is undisputed that the Guideliner V3 is large enough for a stent to pass through. (Merrill Decl. Ex. 29, 14:12-13; Keith Dep. 241:8-242:24.)

CONCLUSION

For the foregoing reasons, QXM respectfully requests that the Court enter summary judgment that VSI's asserted patent claims are invalid or not infringed by QXM.

Dated: April 10, 2019

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